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FACSIMILE TRANSMISSION

To: U. S. Patent and Trademark Office Attention: Corrected Filing Receipt

Date: February 8, 2005

Fax # 703-308-7751 Pages 17

From: SCULLY, SCOTT, MURPHY & PRESSER

Re : Hisashi Koike, et al.
U.S. Patent Appln. No. 10/502,513
Your Ref: OSP-15982
Our Docket: 18026

COMMENTS:

The Filing Receipt for the above-identified Patent Application has the Title and Total claims incorrec should read:

TITLE: NUCLEIC ACID INFORMATION DETECTION METHOD AN APPARATUS

TOTAL CLAIMS: 40

Please send to us a corrected Filing Receipt with the information as it is shown on the pages to follov

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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY.DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/502,513	07/23/2004	1753	3892	18026	16	50	3

CONFIRMATION NO. 3956

23389
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FILING RECEIPT

OC000000014715019

Date Mailed: 12/14/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

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Domestic Priority data as claimed by applicant

This application is a 371 of PCT/JP03/00668 01/24/2003

Foreign Applications

JAPAN 2002-17272 01/25/2002
JAPAN 2002-247023 08/27/2002

Projected Publication Date: 03/17/2005

Early Publication Request: No

Title

Method and apparatus for detecting nucleic acid data → wrong

Preliminary Class

204

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Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

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FORM PTO-1390 (Modified) (REV. 11-2000) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	
18026	
U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR	
INTERNATIONAL APPLICATION NO. PCT/JP03/00668	INTERNATIONAL FILING DATE 24 January 2003 (24.01.2003)
PRIORITY DATE CLAIMED 25 January 2002 (25.01.2002) *	

TITLE OF INVENTION
NUCLEIC ACID INFORMATION DETECTION METHOD AND APPARATUS

APPLICANT(S) FOR DO/EO/US
Hisashi Koike; Tomonori Nagaoka; Takatomo Satoh; Yoshioki Kaneko; Midori Hatanaka; Morinao Fukuoka; Hiroko Sakamoto; Hiroyuki Yonekawa

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☒ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☒ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. ☒ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☒ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 20 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☒ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☒ Express Mail Label No. EL871025149US

03P00080
09P-15982 US

Docket: 18026

PTO/SB/106 (5-00)
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Declaration and Power of Attorney for Patent Application

特許出願宣言書及び委任状

Japanese Language Declaration

日本語宣言書

私は、以下に記名された発明者として、ここに下記の通り宣言する：	As a below named inventor, I hereby declare that:
私の住所、郵便の宛先そして国籍は、私の氏名の後に記載された通りである。	My residence, post office address and citizenship are as stated next to my name.
下記の名称の発明について、特許請求範囲に記載され、且つ特許が求められている発明主題に関して、私は、最初、最先且つ唯一の発明者である（唯一の氏名が記載されている場合）か、或いは最初、最先且つ共同発明者である（複数の氏名が記載されている場合）と信じている。	I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled
	NUCLEIC ACID INFORMATION DETECTION METHOD AND APPARATUS
上記発明の明細書はここに添付されているが、下記の欄がチェックされている場合は、この限りでない：	the specification of which is attached hereto unless the following box is checked:
☐ _____ の日に出願され、 この出願の米国出願番号またはＰＣＴ国際出願番号は、 _____ であり、且つ _____ の日に補正された出願（該当する場合）。	☒ was filed on January 24, 2003 as United States Application Number or PCT International Application Number PCT/JP03/00668 and was amended on July 8, 2003 (if applicable).
私は、上記の補正書によって補正された、特許請求範囲を含む上記明細書を検討し、且つ内容を理解していることをここに表明する。	I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.
私は、連邦規則法典第３７編規則１．５６に定義されている、特許性について重要な情報を開示する義務があることを認める。	I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Hisashi Koike, et al.	**Examiner:**	Unassigned
Serial No:	To be assigned	**Art Unit:**	Unassigned
Filed:	Herewith	**Docket:**	18026
For:	NUCLEIC ACID INFORMATION DETECTION METHOD AND APPARATUS	**Dated:**	July 23, 2004

Mail Stop PCT
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Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT

Sir:

In connection with the above-identified patent application, kindly enter the following preliminary amendment prior to examination.

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

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Date of Deposit: July 23, 2004

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: July 23, 2004

Thomas Spinelli

IN THE SPECIFICATION:

Please amend the paragraph beginning on page 27, line 31 as follows:

For the base sequence of K-ras oncogene, a database such as the GenBank was referenced, and probes (SEQ ID NO:56 to 62, 63 to 69, 70 to 76, 77 to 83) were solid-phased onto the microarray. In order to make the layout shown in FIG. 13, the composed probes were spotted using a micro dispersion system using a piezo device. At the spot 1 in FIG. 13, a 20mer sense strand probe corresponding to K-ras natural sequence (Wt) (SEQ ID NO:56) was arranged. At the spot 2, a 20mer sense strand probe corresponding to K-rasArg mutant (SEQ ID NO:57) was arranged. At the spot 3, a 20mer sense strand probe corresponding to K-rasCys mutant (SEQ ID NO:58) was arranged. At spots 4 to 7, 20mer sense strand probes corresponding to SEQ ID NOs 59-62, respectively were arranged. At the spot 8, a 20mer anti-sense strand probe corresponding to K-rasWt (SEQ ID NO:63) was arranged. At spots 9 to 14, 20mer anti-sense probes, corresponding to SEQ ID NOs 64-69 respectively, are arranged. At the spot 15, a 17mer sense strand probe corresponding to K-rasWt (SEQ ID NO:70) were arranged. At spots 16-21, 17mer sense probes, corresponding to SEQ ID NOs 71-76 respectively, were arranged. At the spot 22, a 17mer anti-sense strand probe corresponding to K-rasWt (SEQ ID NO:77) was arranged. At spots 23-28, 17mer anti-sense probes, corresponding to SEQ ID NOs 78-83, were arranged.

IN THE CLAIMS:

1. (Original) A nucleic acid information detection method wherein a target nucleic acid and probes made solid phase on a carrier and having a complementary sequence with at least a portion of said target nucleic acid sequence are contacted with each other in order to form hybrids between said target nucleic acid and said probes, and the amount of signal generated depending on the amount of hybrids is measured in order to detect the information on the target nucleic acid,

said method including kinetically obtaining data of said signal.

2. (Original) A nucleic acid information detection method according to claim 1, wherein obtaining the data of said signal is performed while changing a measurement condition or a detection condition of a reaction.

3. (Original) A nucleic acid information detection method according to claim 2, wherein obtaining the data of said signal is performed while changing at least one of; a reaction temperature, a composition, a volume, and a type of reaction solution.

4. (Original) A nucleic acid information detection method according to claim 3, wherein said change is for the reaction temperature.

5. (Original) A nucleic acid information detection method wherein a perfect matched probe having a perfect complementary sequence with respect to at least part of a target nucleic acid sequence, and one or more types of imperfectly matched probes having at least one part of the perfect matched probe mutated are contacted with said target nucleic acid in order to form hybrids between said target nucleic acid, and said perfect matched probe or

said imperfect matched probes, so that the information on the target nucleic acid can be detected based on a difference in binding strength of the hybrids,

said method including kinetically obtaining data of said signal while changing continuously or stepwise the condition for measuring or detecting the signal from said hybrids.

6. (Original) A nucleic acid information detection method according to claim 5, wherein obtaining the data of said signal is performed while changing at least one of; a reaction temperature, a composition, a volume, and a type of reaction solution.

7. (Original) A nucleic acid information detection method according to claim 6, wherein said change is for the reaction temperature

8. (Original) A nucleic acid information detection method according to claim 7, wherein said change of the reaction temperature is to increase the temperature from a temperature lower than a Tm value of the hybrids to be detected to a temperature higher than the Tm value.

9. (Original) A nucleic acid information detection method according to claim 7, wherein said change of the reaction temperature is a temperature cycle of one or more times comprising increase and decrease between a temperature lower than the Tm value to a temperature higher than the Tm value.

10. (Currently Amended) A nucleic acid information detection method according to ~~either~~ claim 8 ~~or claim 9~~, including a step of measuring a maximum value of the signal strength while increasing said temperature.

11. (Currently Amended) A nucleic acid information detection method according to ~~either~~ claim 8 ~~or claim 9~~, including a step of measuring an amount of change in the signal strength while increasing said temperature.

12. (Original) A nucleic acid information detection method according to any one of claim 5 through claim 11, further comprising the steps of continuously or stepwise increasing the temperature at which a signal from said hybrid is measured, measuring the change in the signal strength from said hybrid between respective temperatures, and maintaining the temperature when the amount of change starts to decrease.

13. (Currently Amended) A nucleic acid information detection method according to any one of claim 1 through claim ~~12~~ 11, wherein in an identical system where identical reaction conditions are applicable, a plurality of types of probes are used in order to detect the information on a plurality of types of nucleic acids at the same time.

14. (Currently Amended) A nucleic acid information detection method according to any one of claim 1 through claim ~~13~~ 11, wherein said probes are a plurality of types of probes having a plurality of types of sequences and said probes have mutually overlapped sequences.

15. (Currently Amended) A nucleic acid information detection method according to any one of claim 1 through claim ~~14~~ 11, wherein said probes having a plurality of types of sequences comprise overlapping probes of; a perfect matched probe having a perfect complementary sequence at least partially with said target nucleic acid sequence, one or more types of imperfect matched probes having at least one partial mutation in said perfect

matched probe, and said perfect matched probe and said imperfect matched probe having an extended or shortened base sequence on both ends or one end.

16. (Currently Amended) A nucleic acid information detection method according to any one of claim 1 through claim ~~15~~ 11, further comprising a step of comparing an analysis result of a probe group having a lower Tm value among the overlapping probes with an analysis result of a probe group having a higher Tm value, thereby deciding the nucleic acid information.

17. (Currently Amended) A nucleic acid information detection method according to any one of claim 1 through claim ~~16~~ 11, wherein the probes have sequences (SEQ ID NO: 59 to 69) comprising 20mer base sequences for analyzing K-ras codon12.

18. (Currently Amended) A nucleic acid information detection method according to any one of claim 1 through claim ~~17~~ 11, wherein the probes have sequences (SEQ ID NO: 70 to 83) comprising 17mer base sequences for analyzing K-ras codon12.

19. (Currently Amended) A nucleic acid information detection method according to any one of claim 1 through claim ~~18~~ 11, wherein the probes consist of probes having sequences of (SEQ ID NO: 56 to ~~83~~ 69) ~~17mer~~ 20mer base sequences for analyzing K-ras codon12, and probes having sequences of (SEQ ID NO: 70 to 83) ~~20mer~~ 17mer base sequences for analyzing K-ras codon12.

20. (Currently Amended) A nucleic acid information detection method according to any one of claim 1 through claim 19 11, wherein said hybrid formation is

performed by making a liquid sample including a target nucleic acid contact with a probe fixed onto a porous body.

21. (Original) A nucleic acid information detection method according to claim 20, further comprising a step of making said liquid sample reciprocate once or a plurality of times in said porous body.

22. (Currently Amended) A nucleic acid information detection method according to any one of claim 1 through claim ~~21~~ 11, wherein said signal is detected based on detection of a fluorescent marker.

23. (Currently Amended) A nucleic acid information detection method according to any one of claim 1 through claim ~~22~~ 11, wherein said target nucleic acid is any one of an oncogene, an intracellular drug resistance gene, a cell cycle regulator gene, and an apoptosis related gene, or a combination of these.

24. (Original) A nucleic acid information detection apparatus comprising: a sample storage container for containing a sample including a target nucleic acid; a nucleic acid reaction carrier including a porous structure which can fix said nucleic acid and connected to said container; a driving device for mobilizing said sample under control, between said container and said nucleic acid reaction carrier without leaking; a temperature control device for controlling a reaction temperature on said reaction carrier; and a device for detecting a signal from a hybrid between a target nucleic acid and probes formed on said porous structure.

25. (Original) A nucleic acid information detection apparatus according to claim 24, further comprising: one or more solution storage containers for storing solutions connected to said nucleic acid reaction carrier and to contain types of solutions different to the sample solution including the target nucleic acid; and a device which appropriately mixes the various solutions contained in said solution storage containers and sends these to said nucleic acid reaction carrier.

26. (Original) A nucleic acid information detection apparatus according to either one of claim 24 and claim 25, wherein said target nucleic acid is any one of an oncogene, an intracellular drug resistance gene, a cell cycle regulator gene, and a apoptosis related gene, or a combination of these.

27. (New) A nucleic acid information detection method according to claim 9, including a step of measuring a maximum value of the signal strength while increasing said temperature.

28. (New) A nucleic acid information detection method according to claim 9, including a step of measuring an amount of change in the signal strength while increasing said temperature.

29. (New) A nucleic acid information detection method according to claim 27 or 28, further comprising the steps of continuously or stepwise increasing the temperature at which a signal from said hybrid is measured, measuring the change in the signal strength from said hybrid between respective temperatures, and maintaining the temperature when the amount of change starts to decrease.

30. (New) A nucleic acid information detection method according to claim 27 or 28, wherein in an identical system where identical reaction conditions are applicable, a plurality of types of probes are used in order to detect the information on a plurality of types of nucleic acids at the same time.

31. (New) A nucleic acid information detection method according to claim 27 or 28, wherein said probes are a plurality of types of probes having a plurality of types of sequences and said probes have mutually overlapped sequences.

32. (New) A nucleic acid information detection method according to claim 27 or 28, wherein said probes having a plurality of types of sequences comprise overlapping probes of; a perfect matched probe having a perfect complementary sequence at least partially with said target nucleic acid sequence, one or more types of imperfect matched probes having at least one partial mutation in said perfect matched probe, and said perfect matched probe and said imperfect matched probe having an extended or shortened base sequence on both ends or one end.

33. (New) A nucleic acid information detection method according to claim 27 or 28, further comprising a step of comparing an analysis result of a probe group having a lower Tm value among the overlapping probes with an analysis result of a probe group having a higher Tm value, thereby deciding the nucleic acid information.

34. (New) A nucleic acid information detection method according to claim 27 or 28, wherein the probes have sequences (SEQ ID NO: 59 to 69) comprising 20mer base sequences for analyzing K-ras codon12.

35. (New) A nucleic acid information detection method according to claim 27 or 28, wherein the probes have sequences (SEQ ID NO: 70 to 83) comprising 17mer base sequences for analyzing K-ras codon12.

36. (New) A nucleic acid information detection method according to claim 27 or 28, wherein the probes consist of probes having sequences of (SEQ ID NO: 56 to 69) 20mer base sequences for analyzing K-ras codon12, and probes having sequences of (SEQ ID NO: 70 to 83) 17mer base sequences for analyzing K-ras codon12.

37. (New) A nucleic acid information detection method according to claim 27 or 28, wherein said hybrid formation is performed by making a liquid sample including a target nucleic acid contact with a probe fixed onto a porous body.

38. (New) A nucleic acid information detection method according to claim 37, further comprising a step of making said liquid sample reciprocate once or a plurality of times in said porous body.

39. (New) A nucleic acid information detection method according to claim 27 or 28, wherein said signal is detected based on detection of a fluorescent marker.

40. (New) A nucleic acid information detection method according to claim 27 or 28, wherein said target nucleic acid is any one of an oncogene, an intracellular drug resistance gene, a cell cycle regulator gene, and an apoptosis related gene, or a combination of these.

REMARKS

It is respectfully requested that this Preliminary Amendment be entered in the above-identified application prior to examination.

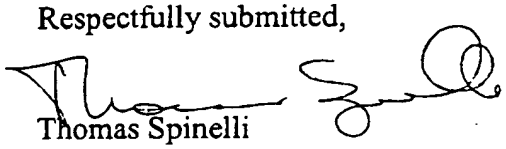
By means of the present Preliminary Amendment, the claims have been amended in accordance with accepted U.S. practice. Specifically, the claims have been amended to comply with U.S. practice in not having a multiple dependent claim depend from another multiple dependent claim. No new matter has been entered into the disclosure by way of such amendment.

Furthermore, by way of the present preliminary amendment, new claims 27-40 have been added to further define the patentable invention. New claims 27-40 are fully supported in the original disclosure. Thus, no new matter has been entered into the disclosure by way to the addition of new claims 27-40.

Lastly, in an effort to clarify the description, the Applicants have amended the application in Example 6 to identify the probes arranged at each spot. The Applicants have also amended the Sequence Listing at SEQ ID NOs: 10, 12, 13, 15-25 and 56-83 to clarify that the sequence provided therein are primers or probes and therefore properly designated as "Artificial Sequence" pursuant to 37 C.F.R. §1.821 et seq. Support for this amendment is found in the Examples. No new matter has been added.

It is respectfully requested that this Preliminary Amendment be entered in the above-identified application prior to examination.

Respectfully submitted,



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